MDCG 2023-7
Facts and Fiction

Clarifying key exemptions from clinical investigations for implantable and class III medical devices and mastering the art of demonstrating equivalence

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Clinical evaluation is mandatory for all medical devices under MDR

Clinical evaluation is defined in Art. 2(44) of the MDR as a

[…] systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer […]

A clinical evaluation shall be performed for all devices under the MDR.

Acc. to Art. 61 (1),

Confirmation of conformity with relevant general safety and performance requirements *set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I,* ***shall be based on clinical data providing sufficient clinical evidence****, including where applicable relevant data as referred to in Annex III.*

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Is the conduct of clinical investigations the only appropriate pathway to demonstrate conformity with GSPRs for class III and implantable devices?

The clinical evaluation of implantable and class III medical devices **shall** always be based on clinical data **typically** coming from clinical investigations.

However, in some cases and under specific conditions, the conduct of a clinical investigation to collect the necessary clinical data may not be necessary.

Art. 61(4-6) of MDR describe the 3 cases when the conduct of clinical investigations may not be mandatory and other sources of clinical data can be used to demonstrate conformity of the medical device with the relevant safety and performance requirements.

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Articles 61(4-6) of MDR

4. In the case of implantable devices and class III devices, clinical investigations shall be performed, except if:

— the device has been designed by modifications of a device already marketed by the same manufacturer,

— the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and

— the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

In this case, the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

In addition, clinical investigations need not be performed in the cases referred to in paragraph 6.

5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

— the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and

— the original clinical evaluation has been performed in compliance with the requirements of this Regulation,

and the manufacturer of the second device provides clear evidence thereof to the notified body.

6. The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

(a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation:

— is based on sufficient clinical data, and

— is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or

(b) that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

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What is MDCG 2023-7 talking about?

MDCG 2023-7

Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR

and on

'sufficient levels of access' to data needed to justify claims of equivalence

The MDCG 2023-7 Guidance addresses the following items:

- the cases where implantable and class III devices can be exempted from the requirements for clinical investigations
- in which cases contracts are indeed required to claim equivalence to another manufacturer's device (and use their clinical data);
- how to demonstrate "sufficient levels of access" to the data required for justification of equivalence claims.

👉 By understanding the exemptions and criteria for demonstrating equivalence, manufacturers can more efficiently define their clinical evidence requirements as well as the sources of acceptable clinical data.

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What is MDCG 2023-7 talking about?

CAUTION!

- **Art. 61(4-6) are ONLY referring to class III and implantable devices.**
- **Art. 61(4-6) are NOT a waiver from the requirement to conduct clinical investigations.**
- Devices which are neither class III nor implantable are **outside the scope** of these articles and MDCG 2023-7.
- The need for clinical investigations for lower class devices is determined by the objectives of their clinical evaluation and the sufficiency of existing clinical evidence to meet those objectives (Refer to MDCG 2020-5 and MDCG 2020-6).

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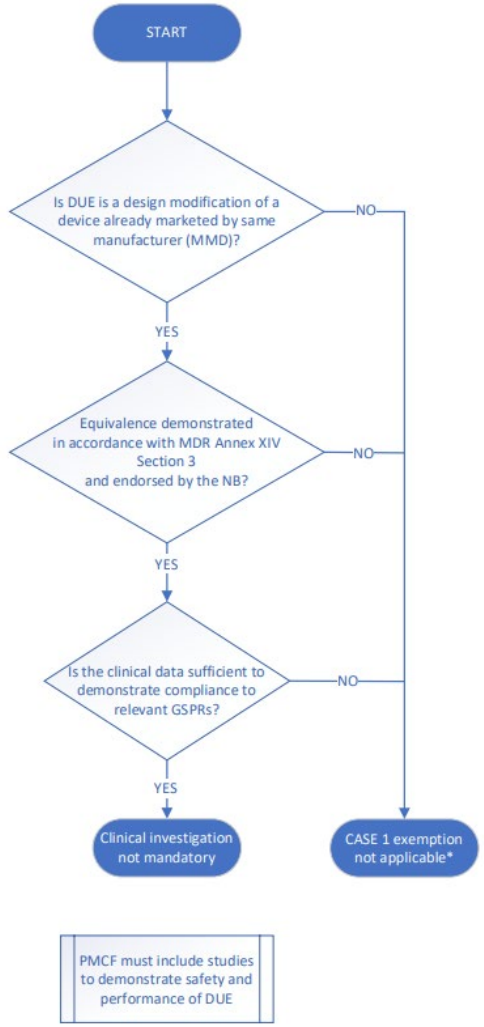
When are clinical investigations not mandatory for class III and implantable devices acc. to Art. 61(4-6)?

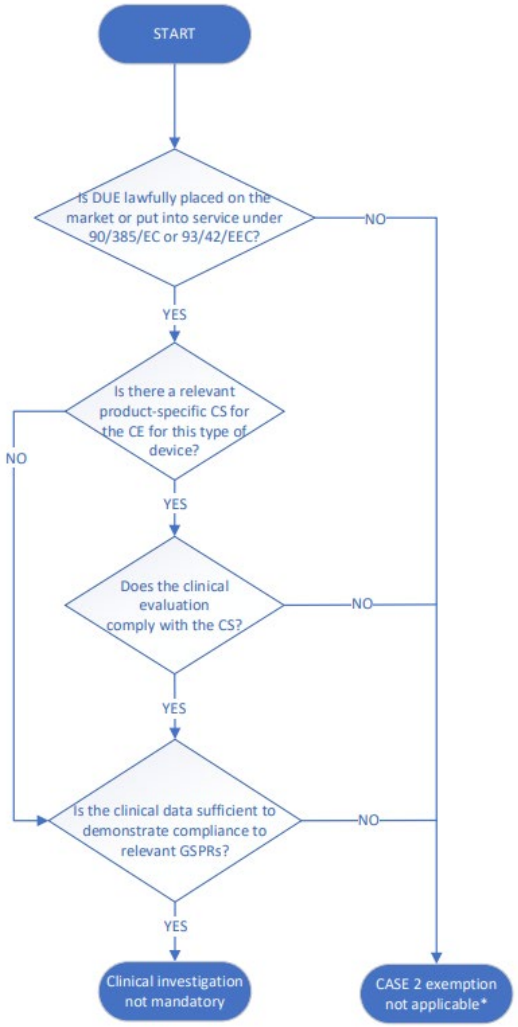


SCENARIO 1 | Art. 61(4), indents 1-3

- DUE has been designed by modifications of a device already marketed by the same manufacturer
- Equivalence is demonstrated between the DUE and the manufacturer's ED in accordance with Section 3 of Annex XIV; demonstration of equivalence has been endorsed by the notified body
- The clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements
- PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the DUE

DUE = Device Under Evaluation
ED = Equivalent Device

When are clinical investigations not mandatory for class III and implantable devices acc. to Art. 61(4-6)?

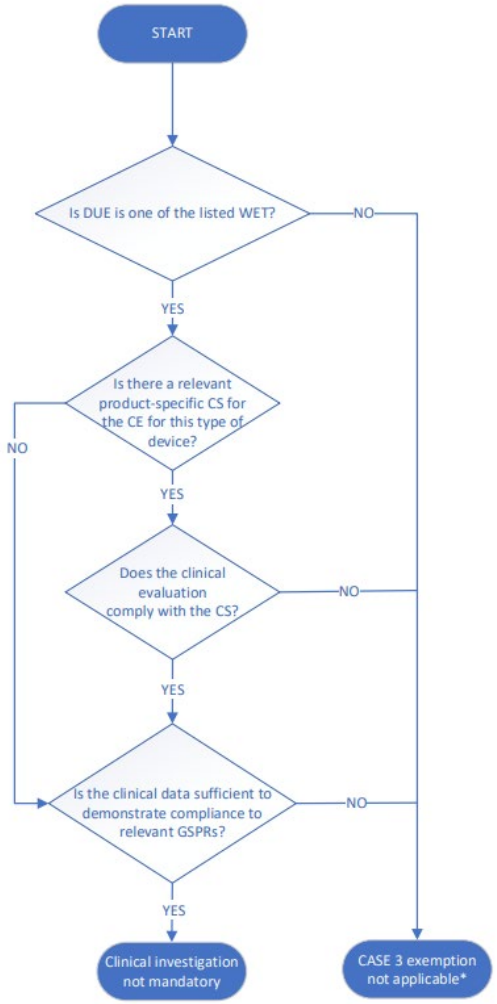


SCENARIO 2 | Article 61(6)(a)

- DUE has been lawfully placed on the market or put into service in accordance with the Directives
- The clinical evaluation is based on sufficient clinical data
- The clinical evaluation is in compliance with the relevant products- specific common specifications for the clinical evaluation of that kind of device, where such a common specification is available

DUE = Device Under Evaluation
ED = Equivalent Device

When are clinical investigations not mandatory for class III and implantable devices acc. to Art. 61(4-6)?



SCENARIO 3 | Article 61(6)(b)

- DUE is one of the listed types of devices: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges,
- plates, wires, pins, clips or connectors
- The clinical evaluation is based on sufficient clinical data
- The clinical evaluation is in compliance with the relevant product-specific common specifications for the clinical evaluation of that kind of device, where such a common specification is available

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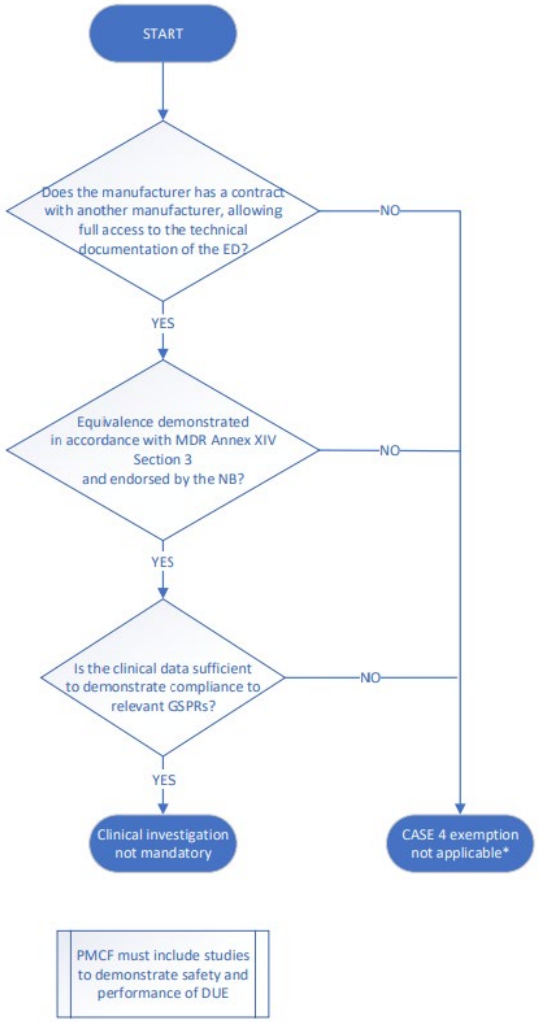
When are clinical investigations not mandatory for class III and implantable devices acc. to Art. 61(4-6)?



SCENARIO 4 | Article 61(5)

- Equivalence is demonstrated between the DUE and the other manufacturer's ED in accordance with Section 3 of Annex XIV

DUE = Device Under Evaluation
ED = Equivalent Device

Points of Interest

CAUTION!

- **Art. 61(4), (5), (6) are independent of one another. In other words, the criteria outlined in one paragraph do not apply to the other paragraphs unless explicitly stated. Specifically, the requirement for a contract as described in Art. 61(5) does not apply to the exemption cases outlined in Art. 61(4) and 61(6).**
- **If a clinical investigation is determined to be mandatory, the MDR does not specify the number or extent of required clinical investigation(s). This determination lies within the responsibilities of the manufacturer. However, as a minimum, mandatory clinical investigation(s) should be understood to mean a pivotal clinical investigation(s) generating pivotal data.**
- **Art. 61(4)-(6) are intended to determine when implantable and class III devices may be exempted from the requirement for premarket clinical investigations and do not discuss whether equivalence may or may not be used as a regulatory pathway.**

How can a manufacturer demonstrate equivalence and sufficient access to an equivalent device's data?

Annex XIV, section 3 of MDR mandates manufacturers to have ***sufficient levels of access to the data*** of the equivalent device in order to claim equivalence.

MDCG 2023-7 clarifies that having a contract is not the only means by which a manufacturer can demonstrate sufficient level of access to the data of the equivalent device.

The guidance proposes a hierarchy for the determination of completeness of access and, therefore, indirectly the strength of the manufacturer's argumentation that they can indeed show sufficient access.

How can a manufacturer demonstrate equivalence and sufficient access to data?

LEVELS OF ACCESS

- Contract with the manufacturer of the equivalent device, allowing full access to the technical documentation on an ongoing basis
- DUE is a design modification of a device already marketed by the same manufacturer
- Rights to DUE acquired with transfer of all relevant design and clinical data at the time of acquisition

- Device with the same design specification and intended purpose is supplied to several manufacturers by the same production subcontractor, and manufacturer has access to the technical specifications necessary to demonstrate technical and biological equivalence
- Comparative analysis and/or testing of the DUE and ED based on samples of both devices coupled with publicly available information

- Device with the same design specification and intended purpose is supplied to several manufacturers by the same production subcontractor, but access to data needed to establish equivalence is only available through publicly available information

- Product specification determined solely through publicly available information

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DUE = Device Under Evaluation
ED = Equivalent Device

What are the PMCF requirements for class III and implantable devices exempted from the requirement to conduct clinical investigations?

The above exemptions, when and if applicable, **do not imply that a manufacturer will be relying on equivalence *[...] in perpetuity [...]* and PMCF activities will be necessary** to demonstrate the safety and performance of the target device.

In cases where PMCF studies must be undertaken as part of the device's certification under the Directives, the exemptions described in the guidance MDCG 2023-7 cannot be used to justify failure to conduct the required PMCF activities.

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Take-home messages

- There can be **some flexibility** in the clinical data sources used by manufacturers to demonstrate the conformity of their devices with GSPRs as **they can practically use all forms of clinical data within the definition of Art 2(48) including clinical data of an equivalent device**. At all cases, proper justification is required about the acceptability and sufficiency of the clinical evidence.

- Although some flexibility has been granted, the PMCF requirements are clearly still applicable for all devices as the primary tool of monitoring and confirming the lifelong safety and performance of medical devices.

- **A manufacturer may use clinical data of an equivalent device without a contract for the legacy MDD and AIMDD devices described in Art 61(6)**, i.e.,

👉 devices based on sufficient clinical data, and in compliance with the relevant product-specific common specifications (where available);
👉 sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant common specifications (where available).

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How can Evnia help?

Headquartered in Denmark, the company current has offices in the UK, Greece, Switzerland and Italy and is servicing life-science clients globally.

It has been certified under ISO 9001:2015 as a Clinical and regulatory affairs consulting agency within the life science industry.

Evnia offers a cluster of interconnected services from the early stages of a medical device's lifecycle until its post-market adulthood.

We support healthcare innovation and promotion of patient safety by providing services in the fields of:

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- 📌 Regulatory Strategy
- 📌 Clinical Development Strategy
- 📌 Post-Market Surveillance
- 📌 Real World Evidence
- 📌 Market Access and Reimbursement
- 📌 EU and UK Representation Services (Authorised Representative & UKCA UKRP)

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